UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,224	08/15/2005	Hiroshi Nagai	1083-7	6249

7590 12/19/2007

Jack Schwartz & Associates
Suite 1510
1350 Broadway
New York, NY 10018

EXAMINER	
ELLIS, SUEZU Y	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,224	NAGAI ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/06, 12/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not

extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on November 13, 2006 and December 13, 2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Referring to Fig. 1, the characters "C", "EC" and "ECg" are not described in the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

On page 5, lines 16-19, the specification discusses the tannin content. However it is unclear how the twithin the range related to the rest of the invention (strychnine and methylcatechin).

On page 5, line 22, the specification recites "IgE generation". However, it is unclear what "IgE" signifies.

Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities:

In claim 1, line 2, "eplgallocatechin-3-O-(3-O-methyl)gallate" is misspelled. It should be "epigallocatechin-3-O-(3-O-methyl)gallate" instead.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

With respect to claims 1-10, since strychnine is a well-known poison and the lethal dosage for a human falls within the range claimed in claims 7 and 8, as demonstrated by a New York Times article ("Strychnine termed as toxic as cyanide but 2 poisons differ"), one of ordinary skill in the art would not associate using strychnine, a known poison, as an anti-allergenic in foods or drinks. Therefore, claims 7 and 8 are considered to be non-enabling.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 1 and 10, it is unclear from the claim language if strychnine is included in the group when applicant recites "from the group consisting of...., and strychnine", or if the food/drink also comprises strychnine as well as the various EGCG/GCG's. Please clarify. If applicant intended for strychnine not to be an optional ingredient, claim language should be rewritten to clearly express that (e.g. food/drink comprising strychnine and one or more selected from the group consisting of...). For examination purposes, strychnine will be considered an optional ingredient within the group.

With respect to claims 1-9, it is unclear what applicant means by "functional food/drink". Please clarify. It is unclear what makes a food or drink functional.

With respect to claim 2, it is unclear from the claim language if applicant is implying that the food/drink comprises EGCG3"Me, GCG3"Me, EGCG4"Me, CG4"Me and strychnine. Please clarify. For examination purposes, claim language will be interpreted as the one or more ingredients selected from the group consisting of EGCG3"Me, GCG3"Me, EGCG4"Me, CG4"Me and strychnine is/are obtained as tea extracts and/or contained in ground tea.

Claims not specifically addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by "Shokuhin Kenkyu Seika Jyouhou" (National Food Research Institute).

With respect to claim 1, "Shokuhin Kenkyu Seika Jyouhou" discloses a beverage comprising epigallocatechin-3-O-(3-O-methyl)gallate (para. 1).

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sano et al. ("Novel Antiallergic Catechin Derivatives Isolated from Oolong Tea", J. Agric. Food. Chem.).

With respect to claims 1-4, Sano et al. discloses a beverage (tea) comprising epigallocatechin-3-O-(3-O-methyl)gallate, wherein the epigallocatechin-3-O-(3-O-methyl)gallate is obtained as tea extract from "Seishin-Taipan", (equivalent to "Seishin dai-pan"), "Benihomare", "Benifuji", "Benfuki" and/or oolong tea leaves (para. starting with "Extraction and Isolation of Compounds 1 (C-1) and 2 (C-2)" and "Catechin Content of Tea Leaves").

With respect to claims 5 and 6, Sano et al. discloses in Fig. 2, an example the content of epigallocatechin-3-O-(3-O-methyl)gallate (C-1) is 241 mg in 0.5 liter (para. starting with "Extraction and Isolation of Compounds 1 (C-1) and 2 (C-2)"). Examiner notes that the daily intake ranges are considered intended use and therefore will not be given patentable weight.

Claims 1-4 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. (EP 1 157 693).

With respect to claims 1-4, Yamamoto et al. discloses a beverage comprising epigallocatechin-3-O-(3-O-methyl)gallate [0014], wherein the epigallocatechin-3-O-(3-O-methyl)gallate is obtained as tea extract from "Seishin-Taipan", (equivalent to "Seishin dai-pan"), "Benihomare", "Benifuji", and/or "Benfuki" tea leaves [0024].

With respect to claim 9, Yamamoto et al. discloses the drink comprises sweetening agents, thereby masking any bitterness the tea may have [0031].

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by "Shokuhin Kenkyu Seika Jyouhou" (article from the National Food Research Institute).

With respect to claim 1 is, "Shokuhin Kenkyu Seika Jyouhou" discloses a beverage comprising epigallocatechin-3-O-(3-O-methyl)gallate (para. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Shokuhin Kenkyu Seika Jyouhou".

With respect to claims 2-4, "Shokuhin Kenkyu Seika Jyouhou" addresses all the limitations of claim 1, however fails to expressly disclose the epigallocatechin-3-O-(3-O-methyl)gallate being obtained as tea extras and/or in ground tea. However, "Shokuhin Kenkyu Seika Jyouhou" does disclose the epigallocatechin-3-O-(3-O-methyl)gallate being obtained from "Seishin-Taipan", (equivalent to "Seishin dai-pan"), "Benihomare", and "Ooba-oolong" (equivalent to "Oba-oolong") tea leaves (para. 2). It would have

been obvious to one or ordinary skill in the art to modify the form of tea (e.g. tea extract, tea leaves, ground tea) depending on the user's preference of tea drinking.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. in view of Humphrey et al. (US 6,036,991).

With respect to claim 10, Yamamoto discloses epigallocatechin-3-O-(3-O-methyl)gallate is derived from tea leaves can be used as such or as powders, or used in combination with drink materials or carriers acceptable for preparation of drink [0030]. However, Yamamoto et al. fails to expressly disclose a tea bag containing the tea leaves. However, it is well known in the art for tea containing epigallocatechin-3-O-gallate being from tea bags, as taught by Humphrey et al. (col. 5, lines 37-41). It would have been obvious design choice to one of ordinary skill in the art to package the tea of Yamamoto in tea bags depending on the user's preference and for ease of use (less clean up than loose tea leaves).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

"Novel Antiallergic Catechin Derivatives Isolated from Oolong Tea", Sano et al., (Journal of Agriculture and Food Chemistry) discloses

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600